

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

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SHIRE DEVELOPMENT LLC, SHIRE  
PHARMACEUTICAL DEVELOPMENT  
INC., COSMO TECHNOLOGIES LIMITED,  
and NOGRA PHARMA LIMITED,

Plaintiffs,

v.

AMNEAL PHARMACEUTICALS LLC,  
AMNEAL PHARMACEUTICALS OF NEW  
YORK, LLC, AMNEAL  
PHARMACEUTICALS CO. (I) PVT. LTD.,  
and AMNEAL LIFE SCIENCES PVT. LTD.,

Defendants.

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Civil No. 15-2865 (RBK/JS)

**OPINION**

**KUGLER**, United State District Judge:

This patent infringement action is brought by Plaintiffs Shire Development LLC, Shire Pharmaceutical Development Inc., Cosmo Technologies Limited, and Nogra Pharma Limited (collectively, “Shire”) against Defendants Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals Co. (I) Pvt. Ltd., and Amneal Life Sciences Pvt. Ltd. (collectively, “Amneal”). This matter is before the Court for claim construction of certain terms contained with U.S. Patent 6,773,720 (the “’720 Patent”) pursuant to *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996) on submission of initial briefs by both parties [Dkt. Nos. 77, 79] and responsive briefs [Dkt. Nos. 87, 89]. The Court held a claim construction hearing (the “Hearing”) on July 25, 2016. (*See* Hr’g Tr. [Dkt. No. 115].) After reviewing the parties’ submissions and hearing arguments of counsel, the Court construes the disputed claim terms as described herein.

## **I. FACTUAL BACKGROUND AND PROCEDURAL HISTORY**

This suit arises from Amneal's submission of an Abbreviated New Drug Application ("ANDA") to the Food and Drug Administration ("FDA"), which, in conjunction with Amneal's Paragraph IV certification under the Hatch-Waxman Act, constituted a technical act of infringement. (Compl. [Dkt. No. 1] ¶ 32); 35 U.S.C. § 271(e)(2)(A); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990); *Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 790 (Fed Cir. 2016). By filing its ANDA, Amneal seeks to market a generic version of Shire's Lialda® product, a drug used to treat inflammatory bowel diseases such as ulcerative colitis and Crohn's disease.

Shire contends that Amneal's product will infringe claims 1 and 3 of the '720 Patent, which state as follows:

1. Controlled-release oral pharmaceutical compositions containing as an active ingredient 5-amino-salicylic acid, comprising:
  - a) an inner lipophilic matrix consisting of substances selected from the group consisting of unsaturated and/or hydrogenated fatty acid, salts, esters or amides thereof, fatty acid mono-, di- or triglycerids, waxes, ceramides, and cholesterol derivatives with melting points below 90° C., and wherein the active ingredient is dispersed both in said the [sic] lipophilic matrix and in the hydrophilic matrix;
  - b) an outer hydrophilic matrix wherein the lipophilic matrix is dispersed, and said outer hydrophilic matrix consists of compounds selected from the group consisting of polymers or copolymers of acrylic or methacrylic acid, alkylvinyl polymers, hydroxyalkyl celluloses, carboxyalkyl celluloses, polysaccharides, dextrans, pectins, starches and derivatives, alginic acid, and natural or synthetic gums;
  - c) optionally other excipients;

wherein the active ingredient is present in an amount of 80 to 95% by weight of the total composition, and wherein the active ingredient is dispersed both in the lipophilic matrix and in the hydrophilic matrix.

3. Compositions as claimed in claim 1, in the form of tablets, capsules, [and] min[i]tablets.

(’720 Patent, col. 6 ll. 7–31, 35–36.)

The parties dispute the scope and meaning of the number of claim terms within claim 1 of the ’720 Patent. These terms are: (1) inner lipophilic matrix; (2) outer hydrophilic matrix; (3) dispersed; (4) wherein the active ingredient is dispersed both in [ ] the [said] lipophilic matrix and in the hydrophilic matrix; (5) consisting of substances; and (6) consists of compounds.<sup>1</sup> The Court exercises jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a).

## II. LEGAL STANDARD

The law of claim construction is well settled. The court begins its analysis with the words of the claim, which “are generally given their ordinary and customary meaning.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (internal quotations omitted). The “ordinary and customary meaning . . . is the meaning that the term would have to a person of ordinary skill in the art [(a “POSITA” or “POSA”)] at the time of the invention.” *Id.* at 1313. The claims are read in the context of the entire patent, including the specification, which “necessarily informs the proper construction of the claims.” *Id.* at 1313, 1316. Then, the court turns to the prosecution history, when provided by the parties, which “can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.” *Id.* at 1317. After exhausting these three sources of evidence, known as the intrinsic evidence, the court may “rely on extrinsic evidence, which

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<sup>1</sup> The parties initially also disputed the meaning of the term “melting point”. However, at the start of the Hearing, the parties informed the Court that they had agreed that no construction was necessary of “melting point” beyond plain and ordinary meaning.

‘consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.’” *Id.* (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed Cir. 1995), *aff’d* 517 U.S. 370 (1996)).

Rulings of the Federal Circuit on issues of claim construction for a given patent are binding on later district courts analyzing the same patent. *See Key Pharms. v. Hercon Labs. Corp.*, 161 F.3d 709, 716 (Fed. Cir. 1998) (reviewing claim construction independently and “recogniz[ing] the national *stare decisis* effect that this court’s decisions on claim construction have”). Additionally, interpretations of other district courts of the same terms in the same patent or patent family are highly relevant and persuasive authority, although not necessarily binding. *See Depomed, Inc. v. Sun Pharma Global FZE*, Civ. No. 11-3553 (JAP), 2012 WL 3201962, at \*4 (D.N.J. Aug. 3, 2012) (giving deference to prior claim constructions in related cases); *see also Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 391 (1996) (“[T]reating interpretive issues as purely legal will promote (though it will not guarantee) intrajurisdictional certainty through the application of *stare decisis* on those questions not yet subject to interjurisdictional uniformity under the authority of the single appeals court.”).

Claim construction “is not for a jury but ‘exclusively’ for ‘the court’ to determine.” *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 835 (2015) (quoting *Markman*, 517 U.S. at 390). “[W]hen the district court reviews only evidence intrinsic to the patent (the patent claims and specifications, along with the patent’s prosecution history), the judge’s determination will amount solely to a determination of law, and the Court of Appeals will review that construction *de novo*.” *Id.* at 841. However, where the court turns to extrinsic evidence and makes factual findings in support of its construction, “this subsidiary factfinding must be reviewed for clear error on appeal.” *Id.*

### III. RELATED CASES

This Court is not the first that has been invited to construe the claims of the '720 Patent. The claims terms in dispute have been construed by multiple district court judges, and the terms “inner lipophilic matrix” and “outer hydrophilic matrix” have been the subject of discussion by the Federal Circuit as well.

Shire filed suit against Watson Pharmaceuticals, Inc. and related entities in 2012, which has resulted in three separate opinions of relevance here. The district court, Judge Middlebrooks, first construed many of the same claims at issue here in *Shire Dev. LLC v. Watson Pharm., Inc.*, No. 12-cv-60862, 2013 WL 174843 (S.D. Fla. Jan. 17, 2013), *rev'd in part*, 787 F.3d 1359 (Fed. Cir. 2015) (“*Watson I*”). Following a bench trial, the generic appealed to the Federal Circuit, challenging the constructions of “inner lipophilic matrix” and “outer hydrophilic matrix.” The Federal Circuit issued an opinion, reported at *Shire Dev. LLC v. Watson Pharm., Inc.*, 746 F.3d 1326 (Fed. Cir. 2014) (“*Vacated Watson*”), which was then vacated by the Supreme Court for the Federal Circuit to consider further in light of the Supreme Court’s decision in *Teva*. *See Shire Dev., LLC v. Watson Pharm., Inc.*, No. 14-206, 135 S. Ct. 1174 (Mem.) (2015). The Federal Circuit on remand from the Supreme Court reversed the district court’s construction of “inner lipophilic matrix” and “outer hydrophilic matrix,” and then remanded for further proceedings. *Shire Dev., LLC v. Watson Pharm., Inc.*, 787 F.3d 1359 (Fed. Cir. 2015), *on remand from* 135 S. Ct. 1174 (Mem.) (2015) (“*Watson II*”).<sup>2</sup> On remand from the Federal Circuit, the district court construed the terms “inner lipophilic matrix” and “outer hydrophilic matrix” consistent with the

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<sup>2</sup> Although the first opinion of the Federal Circuit was vacated, the discussion of claim construction *Watson II* is identical to the discussion in *Vacated Watson*. *Compare Vacated Watson*, 746 F.3d at 1331–34 (Sections III.A and III.B) *with Watson II*, 787 F.3d at 1365–68 (Sections III.A and III.B).

opinion in *Watson II*, and ultimately found the '720 Patent valid and infringed by the generic. *Shire Dev. LLC v. Watson Pharm., Inc.*, No. 12-cv-60862, 2016 WL 1258885 (S.D. Fla. Mar. 28, 2016), *on remand from* 787 F.3d 1359 (Fed. Cir. 2015), *appeal docketed*, No. 16-1785 (Fed. Cir. Apr. 4, 2016) (“*Watson III*”). The generic has again appealed.

Additionally, Shire filed suit against Osmotica Pharmaceutical Corporation and related entities in 2012. The issue of claim construction was first referred to Special Master Berenato, which resulted in a Report and Recommendation to the district court, Judge Totenberg. *Shire Dev. LLC v. Osmotica Pharm. Corp.*, No. 12-cv-904, 2013 WL 11740203 (N.D. Ga. Sept. 25, 2013) (Berenato, S.M.), *adopted-in-part*, Dkt. No. 173 (N.D. Ga. Sept. 25, 2014) (“*Osmotica R&R*”). Following the Federal Circuit’s now-vacated decision in the appeal of *Watson I*, the district court ordered a Supplemental Report and Recommendation on the terms “inner lipophilic matrix” and “outer hydrophilic matrix.” Judge Totenberg then proceeded to construe the claims. *Shire Dev. LLC v. Osmotica Pharm. Corp.*, No. 12-cv-904, Dkt. No. 173 (N.D. Ga. Sept. 25, 2014), *adopting-in-part Osmotica R&R*, 2013 WL 11740203 *and adopting-in-part* Supplemental Report and Recommendation, Dkt. No. 170 (N.D. Ga. Aug. 29, 2014) (“*Osmotica*”).

Shire also filed suit against Mylan Pharmaceuticals, Inc. and related entities in 2012. The district court, Judge Honeywell, construed many of the same claims at issue here. *Shire Dev., LLC v. Mylan Pharms., Inc.*, No. 12-cv-1190, 2015 WL 1345322 (M.D. Fla. Mar. 23, 2015) (“*Mylan*”). That matter is set for a bench trial to begin this fall. Shire has additionally filed suit against Cadila Healthcare Limited, which has resulted in a claim construction opinion reported at *Shire Dev., LLC v. Cadila Healthcare Ltd.*, No. 10-cv-581, 2015 WL 4596410 (D. Del. July 28, 2015) (Jordan, J. by designation) (“*Cadila*”). A bench trial was recently held in that matter, and an opinion is forthcoming.

The parties have additionally noted that a fifth court will shortly be tasked with the same job of claim construction in an upcoming hearing in *Shire Pharm. Dev., Inc. v. Lupin Ltd.*, No. 15-cv-3437 (D. Md. Filed Nov. 10, 2015). Finally, the parties have also made reference to a decision by the U.S. Patent and Trademark Office (the “PTO”) to institute *Inter Partes* Review in *Coalition for Affordable Drugs II LLC v. Cosmo Techs. Ltd.*, IPR2015-00988.<sup>3</sup>

#### IV. DISCUSSION

##### A. “inner lipophilic matrix” and “outer hydrophilic matrix”

These two terms are generally treated as two sides of the same coin. The parties argue the constructions for these two terms together, and the Court will decide them together as well. These two terms have been the most litigated, with the following table summarizing the parties’ proposed constructions and the constructions adopted by other courts, discussing only the term “inner lipophilic matrix” as exemplary of both:

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<sup>3</sup> The decision on claim construction in the inter partes review does not aid this Court, as a district court and the PTO make claim construction decisions under different standards and parameters. *See Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2146 (2016) (approving “the use of the broadest reasonable construction standard in inter partes review, together with use of an ordinary meaning standard in district court”).

Shire Proposed Construction	“a matrix of at least one lipophilic excipient where the matrix itself exhibits lipophilic characteristics and is separate from the outer hydrophilic matrix”
Amneal Proposed Construction	“a matrix that exhibits lipophilic properties and no hydrophilic properties, and that is separate and structurally distinct from the outer hydrophilic matrix”
<i>Watson III</i> 2016 WL 1258885, at *8	“a matrix including at least one lipophilic excipient, where the matrix exhibits lipophilic characteristics and is located within, and separate from, the outer hydrophilic matrix”
<i>Osmotica</i> Slip op. at 16	“a macroscopically homogeneous structure in all its volume that has poor affinity towards aqueous fluids and does not have an affinity for water . . . and wherein the inner lipophilic matrix is separate from the outer hydrophilic matrix”
<i>Mylan</i> 2015 WL 1345322, at *6	“a macroscopically homogenous structure in all its volume that is separate from the outer hydrophilic matrix and that has a poor affinity towards aqueous fluids”
<i>Cadila</i> 2015 WL 4596410, at *4	“a matrix that exhibits lipophilic properties and is separate from the outer hydrophilic matrix”

The parties have agreed that (1) “matrix” shall mean “a macroscopically homogenous structure in all its volume;” (2) “lipophilic” shall mean “poor affinity towards aqueous fluids;” and (3) “hydrophilic” shall mean “has an affinity for water.” (*See* Joint Claim Construction Statement [Dkt. No. 57] at 3.)

The parties generally agree about most of the construction with three sticking points: (1) the so-called “negative limitation” proposed by Amneal which requires that the matrices not exhibit any characteristic of the other (i.e., the lipophilic matrix has no hydrophilic properties, and vice versa); (2) Amneal’s proposed “structurally distinct” requirement; and (3) Shire’s proposed requirement of “at least one . . . excipient.” Both parties argue that their construction is the correct interpretation of the Federal Circuit’s decision in *Watson II*.



## 1. Negative Limitation

This limitation has already been considered in some form by the courts in *Osmotica*, *Mylan*, and *Cadila*. Judge Totenberg in *Osmotica* adopted some form of the negative limitation, *see Osmotica*, slip op. at 15–16, whereas Judge Honeywell and Judge Jordan each rejected the limitation, *see Mylan*, 2015 WL 1345322, at \*5–6; *Cadila*, 2015 WL 4596410, at \*3. In reaching their decisions, each court interpreted the Federal Circuit’s holding that “the matrix that is deemed the ‘lipophilic’ matrix cannot have hydrophilic properties.” *Watson II*, 787 F.3d at 1367.<sup>4</sup>

Relying on that statement from the Federal Circuit, Judge Totenberg in *Osmotica* held that “a substance that ‘cannot have hydrophilic properties’ cannot have an affinity for water.” *Osmotica*, slip op. at 15–16. However, she did not think that meant the inner lipophilic matrix was foreclosed from “any affinity for water.” *Id.* (emphasis in original). Thus, the court’s construction included the limitation that the matrix “does not have an affinity for water,” which left open the possibility for *some* affinity for water. *Id.* at 16.

On the other hand, Judge Honeywell in *Mylan* determined that adding the negative limitation would read too much into the statement of the Federal Circuit. Acknowledging her departure from *Osmotica*, she found that the negative limitation was not mandated by *Watson II*. *Mylan*, 2015 WL 1345322, at \*5–6. The court interpreted the language in *Watson II* as “simply restating the fact that a matrix that has significant amounts of hydrophilic elements mixed with lipophilic elements—and that consequently does not have an *overall* poor affinity towards aqueous fluids—cannot be deemed the ‘lipophilic’ matrix. *Id.* at \*5 (citation omitted). The court

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<sup>4</sup> The courts in *Mylan* and *Osmotica* cite to *Vacated Watson*. However, this section was identical in both the vacated opinion and the opinion on remand from the Supreme Court as noted in note 2, *supra*.

determined that “a matrix that is lipophilic . . . is necessarily one that is not hydrophilic. Therefore, defining a lipophilic matrix as one that is additionally not hydrophilic is circular and, rather than adding precision, adds only confusion.” *Id.*

Judge Honeywell additionally relied on the Federal Circuit’s later holding that “[w]hether or not a composition infringes when there is a trace of hydrophilic molecules in the inner [lipophilic matrix] because of the mixing step inherent in the manufacturing process, for example, is a question for the fact finder.” *Watson II*, 787 F.3d at 1637–68. The court determined that if the negative limitation were to hold true, and that “a lipophilic matrix literally cannot have *any* hydrophilic properties, then an inner composition with trace amounts of hydrophilic molecules would not infringe as a matter of law,” and the Federal Circuit’s holding would be superfluous. *Mylan*, 2015 WL 1345322, at \*5.

In noting her disagreement with the court in *Osmotica*, Judge Honeywell explained that she “respectfully disagree[d]” that *Watson II* “would mandate such limitations.” *Id.* at \*6. She further commented that “after carefully reviewing the *Osmotica* opinion, the Court remain[ed] unclear as to what these negative limitations help clarify.” *Id.*

When faced with the negative limitation in *Cadila*, Judge Jordan mostly adopted the reasoning of Judge Honeywell in *Mylan*. *Cadila*, 2015 WL 4596410, at \*3. He determined that “adding [the negative] limitation would be, as the *Mylan* court noted, redundant and potentially confusing.” *Id.* He also noted his departure from the construction provided in *Osmotica*. *Id.* at \*3 n.4.

Amneal here does not present any new or compelling argument that would justify departure from the decisions in *Mylan* and *Cadila*. Amneal points to no intrinsic evidence from the claims, specification, or prosecution history that would dictate inclusion of the negative

limitation. Instead, Amneal relies on the same language from *Watson II* that was distinguished in *Mylan* and *Cadila*, as well as its expert declaration. (Defs.’ Opening Br. at 14, 17–18.<sup>5</sup>) The intrinsic evidence does not support adding in the negative limitation, and including it would be redundant and confusing as reasoned by the courts in *Mylan* and *Cadila*. Therefore, the Court declines to adopt this portion of Amneal’s proposed construction.

## 2. “structurally distinct”

The parties are in agreement that the matrices must be separate. The dispute between them is whether the matrices must also be “structurally distinct.” The dispute centers around the proper interpretation of the statements of the Federal Circuit regarding the separate nature of the matrices.

Initially, in *Watson I*, Judge Middlebrooks rejected the generic’s position that the inner and outer matrices must be “separate and distinct.” *Watson I*, 2013 WL 174843, at \*5. The Federal Circuit reversed this portion of the decision, holding that “the claims require the inner lipophilic matrix to be separate, *if not distinct*, from the outer hydrophilic matrix. . . . The separation of these elements within the claims indicates that the claim requires two separate matrices.” *Watson II*, 787 F.3d at 1366 (emphasis added). The court also held that the intrinsic evidence “compel[s] a claim construction which requires that the inner lipophilic matrix is separate from the outer hydrophilic matrix.” *Id.*

Amneal takes the position that “structurally distinct” must be included in the construction in order to give effect to the holding that “the construction of ‘inner lipophilic matrix’ requires the *inner volume to be separate from the outer volume*.” (Defs.’ Opening Br. at 16 (quoting

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<sup>5</sup> Neither Amneal’s Opening Briefs nor Amneal’s Reply Brief is paginated, despite having a table of contents and a table of authorities. The page cites herein are to the ECF page numbers.

*Watson II*, 787 F.3d at 1367 (emphasis added in quoting source)).) Amneal further argues that the only way for the inner volume to be separate from the outer volume is for the two volumes to be “structurally distinct,” thus necessitating the inclusion of the term in its proposed construction. (*Id.* at 16–17.) Shire responds that Amneal’s construction is without basis in the intrinsic record, and at odds with the decision of *Watson II* that ultimately did not mandate that the matrices be distinct. (Pls.’ Opening Br. at 8–9.) Shire further responds that the holding only requires that “the matri[ces] must occupy separate volumes and exhibit separate compositional characteristics.” (*Id.* at 8.)

The dispute stems from whether Federal Circuit in holding “if not” really meant “and also.” The Court concludes they did not. Amneal argued at the Hearing, using a real world example, that if someone says “That argument is silly, *if not* ridiculous,” then what that person really means is “That argument is silly *and also* ridiculous.” (See Hr’g Tr. at 38:24–39:8.) However, in the Court’s own experience, that is not what is being said. What it means is, “That argument is silly and just short of being ridiculous.” If anything, the holding that the matrices are “separate, if not distinct” means that their separation falls just short of requiring the distinction Amneal seeks to impart in adding this limitation. But, the Court does not decide that today.

Much as the negative limitation discussed in Section IV.A.1, *supra*, is redundant and possibly adds confusion, so does the “structurally distinct” limitation. The Court also notes that based on the briefing and the arguments presented at the Hearing, the dispute appears to be an issue of infringement, rather than claim construction. The addition of “structurally distinct” above and beyond the agreed-upon “separate” requirement finds no basis in the claims,

specification, or prosecution history. The extrinsic evidence cited by Amneal also does not support its inclusion. Thus, the Court declines to adopt this portion of Amneal's construction.

### 3. “at least one . . . excipient”

Finally, Amneal argues that by including “at least one . . . excipient,” Shire is attempting not only to impose the same “at least one” limitation from “consisting of substances”/“consists of compounds” that Amneal contests,<sup>6</sup> but also to improperly read “substance”/“compound” as “excipient.” (Defs.’ Opening Br. at 18–20; Defs.’ Resp. Br. at 13–14.) Shire never directly responds to this issue in briefing or at the Hearing.

Including this limitation would unnecessarily confuse the issues and import an unnecessary limitation into the construction. The Court does not necessarily agree that “substance”/“compound” does not have the same meaning as “excipient” here, but it is not necessary to reach a determination on that issue. The plain language of the claim makes clear that the matrix (either the inner lipophilic one or the outer hydrophilic one) must consist of substances or compounds as recited within the claim. (’720 Patent, col. 6 ll. 10–25.) The limitation does not add anything to the understanding of what constitutes an “inner lipophilic matrix” or “outer hydrophilic matrix” beyond reading in limitations that occur later in the claim. Including it would be redundant and unnecessarily confusing based on the intrinsic evidence.

Accordingly, the Court construes the terms as follows: (1) “inner lipophilic matrix” means “a matrix that exhibits lipophilic properties and is separate from the outer hydrophilic matrix”; and (2) “outer hydrophilic matrix” means “a matrix that exhibits hydrophilic properties and is separate from the inner lipophilic matrix.”

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<sup>6</sup> This is discussed in Section IV.D.1, *infra*.

**B. “dispersed”**

The parties have proposed the following constructions for this term, and other courts have construed this term as summarized in the below table:

Shire Proposed Construction	“sufficiently mixed to incorporate one substance with another”
Amneal Proposed Construction	“homogeneously mixed or combined”
<i>Watson I</i> 2013 WL 174843, at *6	“sufficiently mixed to incorporate one substance with another”
<i>Osmotica</i> Slip op. at 18	“sufficiently mixed to incorporate one substance within another”
<i>Mylan</i> 2015 WL 1345322, at *7	plain and ordinary meaning; declined to construe because generic did not propose a construction that would require homogeneity
<i>Cadila</i> 2015 WL 4596410, at *6	“sufficiently mixed to incorporate one substance into another”

The dispute between the parties with respect to this term is whether something must be “homogeneous” to be “dispersed.” Amneal makes two arguments in favor of its position. First, Amneal points to the specification, and cites the numerous instances where the specification requires “homogeneous dispersion.” (Defs.’ Opening Br. at 26–27 (citing ’720 Patent, col. 3 ll. 14–17, col. 3 ll. 42–45, col. 4 ll. 10–12, col. 4 ll. 34–43, col. 4 ll. 55–64, col. 5 ll. 8–18, and col. 5 ll. 31–40); Defs.’ Resp. Br. at 23.) Second, Amneal points to the prosecution history of the ’720 Patent, specifically to when claim 1 was amended to replace the term “at least partly inglobated” with the word “dispersed,” the comments accompanying the amendment, and the examiner’s amendment in ultimately allowing the claims . (Defs.’ Opening Br. at 24–26 (citing

Amendment of October 9, 2003 (Defs.’ Ex. 1 [Dkt. No. 77-3]); Notice of Allowance (Defs.’ Ex. 2 [Dkt. No. 77-6])); Defs.’ Resp. Br. at 22–23.)

Shire responds that homogeneity is not required based on the specification, and also based on extrinsic dictionary evidence. (Pls.’ Opening Br. at 13–15 (citations omitted).) Shire further responds that the intrinsic evidence cited by Amneal actually supports Shire’s position, and undercuts Amneal’s position. (Pls.’ Resp. Br. at 10–12; *see also* Hr’g Tr. at 30:22–31:8.)

Every court confronted with this issue has concluded that “dispersed” does not require homogeneity, and this Court agrees. The courts in *Watson I*, *Osmotica*, and *Cadila* adopted constructions that are identical or almost identical with Shire’s proposed construction. *See Watson I*, 2013 WL 174843, at \*6; *Osmotica*, slip op. at 18; *Cadila*, 2015 WL 4596410, at \*5–6. Additionally, although Judge Honeywell in *Mylan* ordered that the term be given its plain and ordinary meaning, she also rules that “dispersed” did not require homogeneity. *Mylan*, 2015 WL 1345322, at \*7.

In *Watson I*, Judge Middlebrooks rejected the argument made by the generic citing to the specification in support of requiring homogeneity. *Watson I*, 2013 WL 174843, at \*6. Amneal cites to the same specification evidence here. (*See* Defs.’ Opening Br. at 26–27 (citations omitted).) The court noted—as argued here in opposition by Shire—that the specification referred several times to “homogeneous dispersion,” (*e.g.*, ’720 Patent, col. 3 l. 16, col. 4 l.12, col. 4 l. 36), so “if the patentees intended ‘dispersed’ to be construed to mean ‘homogeneously dispersed,’ then stating ‘homogeneous dispersion’ in the specification would be redundant.” *Watson I*, 2013 WL 174843, at \*6. The court also noted the contrasting references to “simple dispersion” elsewhere in the patent, (’720 Patent, col. 1 l. 53), signifying that dispersion could

either simple *or* homogenous. *Watson I*, 2013 WL 174843, at \*6. In *Cadila*, Judge Jordan agreed with this exact reasoning. *Cadila*, 2015 WL 4596410, at \*5–6.

Judge Totenberg did not state any reasoning for her construction in *Osmotica*, which rejected the homogeneous requirement, instead simply adopting the report and recommendation of the special master with respect to this term. *See Osmotica*, slip op. at 18. In the *Osmotica R&R*, the special master rejected the same prosecution disclaimer argument put forth by Amneal here, and concluded that “the intrinsic evidence makes clear that the term ‘dispersed’ was used in order to indicate that the material in question was intermixed with the other material, *i.e.*, one was dispersed in the other.” *Osmotica R&R*, 2013 WL 11740203, at \*18.

Finally, Judge Honeywell in *Mylan* declined to construe the term “dispersed,” but still rejected the idea that homogeneity was required in the term “dispersed.” *Mylan*, 2015 WL 1345322, at \*7. She remarked that:

The Court recognizes that the district courts in *Watson I* and *Osmotica* construed this term according to Shire’s proposed construction. The courts in those cases, however, gave such constructions to distinguish the general concept of “dispersion” from the more specific concept of homogeneous distribution. While the Court agrees that “dispersion” does not necessarily mean that the resulting mixture is homogeneous, neither of *Mylan*’s proposed constructions would erroneously redefine “dispersion” as only homogeneous distribution.

*Id.* However, this Court faces the exact problem Judge Honeywell did not, and which the courts in *Watson I*, *Osmotica*, and *Cadila* did—that the generic wants to conflate “dispersion” and “homogeneous distribution.”

Amneal’s arguments are unavailing, and in line with the courts in *Watson I* and *Cadila*, this Court finds that the evidence from the specification cited by Amneal argues against its position. The Court similarly finds the evidence from the prosecution history does not support



the Amneal’s argument. Accordingly, the Court construes “dispersed” to mean “sufficiently mixed to incorporate one substance with another.”

**C. “wherein the active ingredient is dispersed both [ ] in the [said] lipophilic matrix and in the hydrophilic matrix”**

The parties have proposed the following constructions for this term, and other courts have construed this term as summarized in the below table:

Shire Proposed Construction	“wherein mesalamine is sufficiently mixed to incorporate it within both the lipophilic matrix and the hydrophilic matrix”
Amneal Proposed Construction	“wherein mesalamine is homogeneously mixed or combined within both the inner lipophilic matrix and within the outer hydrophilic matrix”
<i>Watson I</i> 2013 WL 174843, at *6	“wherein mesalamine is sufficiently mixed to incorporate it within both the lipophilic matrix and the hydrophilic matrix”
<i>Osmotica</i> Slip op. at 18	“the active ingredient is sufficiently mixed with the inner lipophilic matrix and the with the outer hydrophilic matrix to incorporate the active ingredient in the inner lipophilic matrix and to incorporate the active ingredient in the hydrophilic matrix”
<i>Cadila</i> 2015 WL 4596410, at *6	“wherein mesalamine is sufficiently mixed to incorporate it within both the lipophilic matrix and the hydrophilic matrix”

The parties here have two disputes: (1) whether “dispersed” here will mean “homogeneous;” and (2) whether Shire’s improperly excludes “inner” and “outer” from its proposed construction.

With respect to the first dispute, the parties have each inserted their proposed construction of “dispersed” into this term. Thus, for the same reasons discussed in Section IV.C, *supra*, the Court rejects Amneal’s proposed construction that incorporates its proposed construction for “dispersed.” *See also Watson I*, 2013 WL 174843, at \*6 (rejecting additional

construction for this term based on the earlier discussion of “dispersed”); *Osmotica R&R*, 2013 WL 11740203, at \*21 (same).

Turning to the second dispute, Amneal argues that by excluding “inner” and “outer” from its proposed construction, Shire is attempting to blur the lines between the matrices. (Defs.’ Opening Br. at 30–31; Defs.’ Resp. Br. at 23–24.) This appears to again go towards Amneal’s concern that Shire is not giving proper respect to the requirement that the matrices be “separate” and is an argument regarding infringement rather than claim construction. Although this issue does not appear to have been squarely addressed in *Cadila*, Judge Jordan there declined to incorporate the words “inner” and “outer” with respect to the matrices, although the generic proposed them in its construction. *Cadila*, 2015 WL 4596410, at \*6.

The Court finds incorporation of the words “inner” and “outer” to be redundant and unnecessary. Accordingly, the Court construes “wherein the active ingredient is dispersed both [ ] in the [said] lipophilic matrix and in the hydrophilic matrix” to mean “wherein mesalamine is sufficiently mixed to incorporate it within both the lipophilic matrix and the hydrophilic matrix.”

#### **D. “consisting of substances” and “consists of compounds”**

The parties have proposed the following constructions for this term, and other courts have construed this term as summarized in the below table. The Court uses only “consisting of substances” in this table as demonstrative of both terms:

Shire Proposed Construction	“consisting of at least one of the recited substances”
Amneal Proposed Construction	“limits the inner lipophilic matrix to at least two of the recited substances”
<i>Watson I</i> 2013 WL 174843, at *7	“containing one or more . . . .”
<i>Osmotica</i> Slip op. at 8	“consisting of at least two . . . .”
<i>Mylan</i> 2015 WL 1345322, at *10	“consisting of two or more . . . .”
<i>Cadila</i> 2015 WL 4596410, at *7	Construed “consisting of” to mean “exclusionary terms specifying that the element contains only what is expressly set forth in a recited list, but not excluding impurities and substances unrelated to said element”

The dispute between the parties centers around (1) whether “consisting of substances” and “consists of compounds” mandates that there be at least two substances/compounds, or only one; and (2) the proper interpretation of “consisting of”/“consists of.” The Court goes through each of these arguments in turn.

### 1. Singular vs. Plural

The positions as taken by the parties are not new to this litigation, and more or less repeat the same arguments presented to the three courts that have already addressed this issue. Amneal submits that the plain language of the claim—“an inner lipophilic matrix consisting of substances<sub>g</sub> selected from the group . . . .” and “said outer hydrophilic matrix consists of compounds<sub>g</sub> selected from the group . . . .”—supports its position. (Defs.’ Opening Br. at 32; Defs.’ Resp. Br. at 24–25.) Amneal argues that the grammatical context mandates that there be at least two substances, because the patent is drafted in the plural. (*Id.*) Amneal additionally

argues that in each of the five examples provided in the specification, there are two lipophilic ingredients for the lipophilic matrix and two hydrophilic ingredients for the hydrophilic matrix. (Defs.’ Opening Br. at 33–34; Defs.’ Resp. Br. at 25.)

Shire responds that the specification provides for only one substance/compound in each of the matrices, as the specification states that “the active ingredient is first inglobated in a low melting *excipient or mixture of excipients*” and that “the inert matrix granules are subsequently mixed together with *one or more* hydrophilic water-swallowable excipients.” (Pls.’ Opening Br. at 18 (citing ’720 Patent, col. 2 ll. 50–59 (emphases added)). With respect to the plain meaning of the claim language, Shire argues that the plural form of substances/compounds was used in order to achieve grammatical consistency, and does not actually mean two or more. (*Id.* at 18–19 (citing *In re Omeprazole Patent Litig.*, 84 F. App’x 76, 80 (Fed. Cir. 2003)).) Additionally, at the Hearing, Shire pointed to a hypothetically drafted claim in which the claim language said only “substance” or “compound” and argued that it would be grammatically incorrect. (Hr’g Tr. at 33:19–34:4.)

The courts that have addressed this issue are split. In *Watson I*, Judge Middlebrooks agreed with Shire, and relied upon the generic method of production language from the specification, which is cited here by Shire, to determine that “the intrinsic record supports [Shire’s] construction of the term, which requires ‘one or more’ of the substances in the list that follows in the claim.” *Watson I*, 2013 WL 174843, at \*7. The court relied on *Versa Corp. v. Ag-Bag Int’l Ltd.*, 392 F.3d 1325, 1330 (Fed. Cir. 2004) which noted “in context, the plural can describe a universe ranging from one to some higher number, rather than requiring more than one item.”

Conversely, Judge Totenberg in *Osmotica* rejected these same arguments. *Osmotica*, slip op. at 5–8. Noting her disagreement with Judge Middlebrooks, and remarking that she did not disagree lightly in view of the desired national uniformity of claim construction, she found the drafting of the claim language in the plural to be dispositive. *Id.* at 7–8 & n.7. In rejecting the specification argument made by Shire, the court found an absence of an intent to redefine the term “substances” or “compounds” to make them singular. *Id.* at 7–8. The court also rejected the grammatical consistency argument and Shire’s reliance on *In re Omeprazole*, finding that the claims at issue in *In re Omeprazole* were distinguishable. *Id.* at 8.

In *In re Omeprazole*, the claim language at issue was “one or more layers of materials” and “one or more layers comprising materials.” 84 F. App’x at 80. The Federal Circuit affirmed the district court’s construction that “materials” could mean just one material, noting that “[t]he use of the plural ‘materials’ . . . represents an effort to match the tense of ‘layers.’” *Id.* Judge Totenberg relied on the fact that the claims at issue here in the ’720 Patent contain no such “one or more” language occurring earlier. *Osmotica*, slip op. at 8 n.8.

Similarly, the court in *Mylan* found the manner in which the claim language was drafted to be dispositive. Judge Honeywell found that using the plain and ordinary meaning of the claim terms required two or more substances/compounds. *Mylan*, 2015 WL 1345322, at \*10. The court noted the grammatical consistency exception argued by Shire, and rejected it, finding that there was no reason “substances”/“compounds” needed to be drafted in the plural to achieve such consistency. *Id.*

The Court agrees with the courts in *Osmotica* and *Mylan*. The plain and ordinary meaning of the claims is that there must be at least two substances/compounds. If the patentee wanted to have only one substance/compound, then the patentee could have drafted the claim

accordingly. Shire's arguments to the specification and grammatical consistency are unavailing. Additionally, the Court notes that Shire's hypothetical claim language put up at the Hearing and referenced above *does* make grammatical sense, further underscoring the Court's determination here.

## 2. "consisting of" and "consists of"

The parties agree that "consisting of" and "consists of" are terms of art with well settled meanings. The disagreement between them appears to stem from what "consisting of" and "consists of" modify. Amneal argues that the impact of this term is to "limit" the matrices to the lists of substances/compounds that follow. (Defs.' Opening Br. at 33; Defs.' Resp. Br. at 28–30.) It appears from Amneal's Reply Brief that Amneal is again concerned that Shire is trying to make its construction read onto some sort of mixed-matrix formulation. (Defs.' Resp. Br. at 29–31.) Shire responds that "consisting of" and "consists of" are not absolute, and in this instance "limit only the elements set forth in each clause but do not exclude all other elements from the claim as a whole." (Pls.' Opening Br. at 16–18; Pls.' Resp. Br. at 14.) This precise dispute has not yet been addressed by any of the other constructing courts.

Shire relies in *Mannesmann Demag Corp. v. Engineered Metal Products Co.*, 793 F.2d 1279, 1282 (Fed. Cir. 1986) in making their argument. (Pls.' Opening Br. at 17.) Shire misreads *Mannesmann* and misapplies grammatical constructs in attempting to find support for its position.

In *Mannesman*, the claim read: "1. A vessel for a metal smelting furnace having a smelting zone including a heat-resistant interior wall . . . characterized by (a) at least a portion of the interior wall of said vessel above the smelting zone *consisting of* at least one cooling pipe coil." *Mannesman*, 793 F.2d at 1281 (emphasis added). The court held "[t]he district court

correctly observed that the phrase ‘consisting of’ appears in clause (a), not the preamble of the claim, and thus limits only the element set forth in clause (a). The court correctly declined to read this usage of ‘consisting of’ as excluding all other elements from the claim as a whole.” *Id.* at 1282. Shire then argues that its claim is drafted in the exact same manner, and because the preamble to claim 1 of the ’760 Patent includes the word “comprising,” it means that all of the elements in the claim “can include substances and compounds other than those identified in clauses (a) and (b).” (Pls.’ Opening Br. at 17.)

It cannot seriously be disputed that in the claim phrase “an inner lipophilic matrix consisting of substances,” (’720 Patent, col. 6 l. 10), the phrase “consisting of” is modifying “an inner lipophilic matrix.” The matrix is being constrained by “consisting of.” Similarly, in the preamble to the claim, “controlled-release oral pharmaceutical compositions containing as an active ingredient 5-amino-salicylic acid, comprising,” (*id.* col. 6 ll. 7–9), the phrase “comprising” is modifying “controlled-release oral pharmaceutical compositions.” The composition as a whole is limited by “comprising,” which is open-ended, meaning that the composition as a whole is not restricted to the elements recited in the claim. However, the matrices, modified by “consisting of,” which is closed-ended, must exclude any ingredient not specified in the claim. *See Conoco, Inc. v. Energy & Envtl. Int’l, L.C.*, 460 F.3d 1349, 1360 (Fed. Cir. 2006) (citing MPEP § 2111.03).

The court in *Mannesman* does not say otherwise. What the court held in *Mannesman* was that the “vessel for a metal smelting furnace” may have elements other than what is recited in the claim, but that the interior wall was limited to the at least one cooling pipe coil. The holding is clear. The other case cited by Shire, *In re Crish*, 393 F.3d 1253, 1257 (Fed Cir. 2004), restates this interpretation, despite Shire’s characterization of the holding. The court there stated “[t]he

reasonable interpretation of the claims containing both of the terms ‘comprising’ and ‘consists’ is that the term ‘consists’ limits [the language it modifies] to the subsequently recited [list], but the earlier term ‘comprising’ means that the claim can included [that list] plus other [elements].” Shire’s arguments to the contrary are absurd and stretch the English language.

However, it is unnecessary to actually construe the phrase “consisting of” or “consists of” due to the well settled legal meaning, other than to make clear that Shire’s understanding is incorrect.

Accordingly, the Court construes the term as follows: (1) “consisting of substances” means “consisting of at least two of the recited substances”; and (2) “consists of compounds” means “consists of at least two of the recited compounds.”

## **V. CONCLUSION**

For the foregoing reasons, the Court will construe the disputed terms of the ’720 Patent consistent with this opinion. An appropriate order accompanies this opinion.

Date: August 2nd, 2016

s/ Robert B. Kugler  
ROBERT B. KUGLER, U.S.D.J.